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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,372	11/21/2003	Gary A. Dahl	EPICEN-09584	3663

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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	PAPER NUMBER
1637	
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01/20/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,372	DAHL ET AL.	
	Examiner	Art Unit	
	CYNTHIA B. WILDER	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *190-192 and 206-219* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *190-192,206,212-216 and 219* is/are rejected.

7)☒ Claim(s) *207-211,217 and 218* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/2/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/2/2010 has been entered. Claims 190, 191 have been amended. Claims 206-219 had been added. Claims 1-189 and 193-205 have been cancelled. Claims 190, 191 and 206-219 are pending. The previous rejections of the prior Office actions are withdrawn in view of the new ground(s) of rejections necessitated by Applicant's amendment.

New Ground(s) of Rejections

Priority

2. Applicant's claim of priority for application 10/153219 which is a continuation-in-part of the instant invention and which claims benefit to 60/292845 filed on 5/22/2001, is acknowledged. However, reviews of the prior filed application recited above do not supported the claims as currently amended. Specifically, no support could be found in the applications recited above which supports the limitations of making a transcription product having a sequence corresponding to a target sequence in a target nucleic acid comprising the steps (a) through (e) as recited in the claims 190 and steps (1) through

(6) recited in the claim 215. Accordingly, the instant application is afforded the instant filing date 11/21/2003 for the purpose of application of prior art.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 212 and 216 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The claims 212 and 216 are indefinite because it is unclear how the limitation "which infects *Thermus Scotoductus*" further defines the method of claims 190 and claim 215 from which they depends or how it defines the structure of the RNA ligase. A clear interpretation of Applicant's intent cannot be ascertained in the context of the claims as currently written.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 190, 192, 206, 215 and 219 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian et al. (PNAS, vol. 98, no. 25, pages 14238-14243, 1999), Lizardi et al. (United States Patent 6,316,229 issued November 13, 2001), and Lorincz et al. (US Patent No. 6,136,535, issued Feb. 2000).

Regarding claims 190 213, 214 and 215, Christian et al. teach methods for making a transcription products corresponding to a target nucleic acid sequence in a target nucleic acid in a sample (entire publication, especially the Abstract), the method comprising the steps of:

(a) primer extending a sense promoter primer to generate a sense promoter-containing first-strand DNA using a target nucleic acid as a template, the sense promoter primer comprising a 5'-end portion that exhibits a sense RNA polymerase promoter sequence and a 3'-end portion that exhibits a sequence complementary to the 3'-end of the target sequence (See Figure 1 and the entire text on p. 14238);

(b) removing the target (see Figure 1 and page 14238, column 1);

(c & d) ligating the 5' and 3' ends of the sense promoter-containing first-strand DNA to each other to obtain a single-stranded circular sense promoter-containing first-strand DNA using a ligase (see 1st sentence of the 2nd column on p. 14239 and see Figure 1);

(3) annealing an anti-sense promoter oligonucleotide to the sense promoter sequence in the sense promoter containing first-strand DNA to obtain a transcription substrate (see 1st sentence of the 2nd column on p. 14239 and Figure 1); and

(4) transcribing the transcription substrate to make a transcription products corresponding to the target nucleic acid sequence (see last sentence of Abstract).

Christian et al. teach DNA and teach transcribing mRNA but do not expressly teach synthesizing the transcription substrates.

Lizardi et al teach a method

Lorincz et al. (Feb. 2000) teach a method comprising the steps of:

(a) obtaining said target nucleic acid (see Figure 1A and see claim 1 or 7 where the target nucleic acids may be a sample; see column 17 lines 14-16: "This process is capable of analyzing multiple samples sequentially or simultaneously"; and see column 3 lines 15 and 16: "Any nucleic acid may be amplified by the method of the present invention");

(b) obtaining said sense promoter primer, the sense promoter primer comprising a 5'-end portion comprising a sense transcription promoter, the sense promoter primer comprising a 5'-end portion that exhibits a sense RNA polymerase promoter sequence (see column 2 lines 56-63), and a 3'-end portion that is complementary to the target (see Figure 1A and see claim 1 or 7);

(c) annealing [hybridizing] the sense promoter primer with the target nucleic acid so as to form a target nucleic acid-sense promoter primer complex (see Figure 1A and see claim 1 or 7);

(4) contacting the target nucleic acid-sense promoter primer complex with a polymerase under polymerization reaction conditions to obtain first-strand nucleic acid that is complementary to the target sequence (see Figure 1A and see claims 1 and 6, or 7 and 11);

(5) ligating the first-strand nucleic acid to itself under ligation conditions so as to obtain circular sense promoter-containing first-strand nucleic acid (see column 4 lines 3 and 4: "Optionally, a ligation reaction may be carried out to fill the gap between the promoter and the template");

(6) obtaining an anti-sense promoter oligonucleotide (see Figure 4 and the circle T7 oligo given there and note that this anti sense promoter is attached to and antibody which an analyte binding substance, ABS);

(7) annealing the anti-sense promoter oligonucleotide to the circular sense promoter-containing first-strand nucleic to obtain a circular transcription substrate (see Figure 4); and

(8) contacting the circular transcription substrate with an RNA polymerase and NTPs under transcription conditions wherein a transcription product is obtained (see Figure 4 for amplification of the circular substrate with polymerase to obtain additional product. And for use of an RNA polymerase see column 3 lines 54-57 and column 23, lines 17-20).

Regarding claim 192, Lorincz et al. (Feb. 2000) teach a method using messenger RNA, mRNA (see column 5 lines 7)) and the DNA polymerase us an enzyme with reverse transcriptase activity (col. 11, line 31).

Regarding claims 206 and 219, Lorincz et al. (Feb. 2000) teach a synthetic promoter comprising a specific-sequence that is complementary to a specific sequence in the target nucleic acid (see Example 1 for synthetic promoter-primer).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of Lorincz et al. by using the sense promoter primer as suggested by Christian et al. with a reasonable expectation of success. The motivation to do so is provided by Christian et al. who teach that use of sense promoter primers in rolling circle amplification improves efficiency in detection of gene copy number and single base mutations up to 90% (see Abstract). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of Christien and Lorincz et al. by transcribing the transcription substrate to make a transcription product as suggested by Lizardi et al. with a reasonable expectation of success. The motivation to do so is provided by Lizardi et al. who teach that cDNA is transcribed into RNA for their disclosed primer extension sequencing procedures and allows for discrimination between two or more forms of the target sequence that differ at a particular nucleotide (see column 69 lines 42-44 and see column 66 lines 46-54). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 190-192, 206, 215 and 219 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 16, 20-21, 23-24, 26, 30 of copending Application No. 10719913. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the instant invention and the claims 7, 16, 20-21, 23-24, 26, 30 of copending Application No. 10719913 because both of the inventions are drawn to method of making a transcription product having a sequence corresponding to a target nucleic acid sequence in a target nucleic acid in a sample, comprising similar steps. The claims of the instant invention only differs from the claims 7, 16, 20-21, 23-24, 26, 30 of copending Application No. 10719913 in that the claims of copending application 10719913 are broader in scope. Thus, the claims of the instant invention falls entirely within the scope of the claims 7, 16, 20-21, 23-24, 26, 30 of copending Application No. 10719913. As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), " a second application-- "containing a broader claim, more generical in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. Miller, 151, U.S. at 198; See Stanley, 214

F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., Titanium metal corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 190-192, 206, 212, 213, 214, 215, 216 and 219 are rejected. Claims 207-211, 217-218 are objected because they depend from rejected claims. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia B. Wilder/
Examiner, Art Unit 1637